

REMARKS

Claims 29-37, 50 and 52-62 are presently pending in this application. Claim 55 has been amended to clarify certain aspects of this claim and to put it in better condition for appeal. A Notice of Appeal is filed concurrently with this paper. This appeal is properly filed because the claims have been rejected many times in several office actions over the last ten years, and in particular the last three Non-Final Office Action dated 11 July 2007, 4 April 2008 and 16 January 2009 have maintained substantially the same substantive rejections of the pending claims. Therefore, claims 29-37, 50 and 52-62 remain pending in the application for appeal to the Board of Patent Appeals and Interferences.

This paper is being filed to present the amendment to claim 55 for appeal, and to address some of the Examiner's statements regarding the Declaration of Dr. Michael D. Laufer, M.D. Under 37 C.F.R. § 1.132 (the "Dr. Laufer Declaration") and the Personal Interview on 25 June 2008, attended by Examiner Shay, Dr. Michael D. Laufer, Ms. Nena Bains and the undersigned representative (the "June 2008 Interview"). The applicant does not concede Examiner Shay's statements and conclusions regarding the Dr. Laufer Declaration, or his statements regarding the June 2008 Interview set forth on pages 2-8 of the Office Action dated 16 January 2009 ("Current Office Action"). Although the applicant will substantively address Examiner Shay's summary, statements and conclusions regarding the Dr. Laufer Declaration in an appeal brief that will be filed in the course of the appeal of the present application, the applicant is compelled to respond in this paper to Examiner Shay's incorrect characterization of the statements made during the June 2008 Interview.

Examiner Shay indicated that the Interview Summary he provided regarding the June 2008 Interview was based on the oral presentation of the affidavit. Examiner Shay was given a draft of the Dr. Laufer Declaration during the June 2008 Interview, and the discussion during the June 2008 Interview addressed Examiner Shay's incorrect characterizations of the applied references and faulty rationale and conclusions that

formed the bases for the Section 103 rejections set forth in the Office Action dated 4 April 2008. Dr. Laufer's presentation during the June 2008 Interview, which is set forth accurately in the Dr. Laufer Declaration, provided facts that directly refute the Examiner's characterizations and conclusions regarding the applied references. For example, claim 50 includes "irradiating walls of an airway of an asthmatic lung with the source of energy at a wavelength and intensity which, over time, causes debulking of smooth muscle tissue of the asthmatic lung and prevents the lung tissue from replicating." In rejecting claim 50, Examiner Shay states on page 10 of the Current Office Action:

It would have been obvious to the artisan of ordinary skill [to] use the method of Clarke (US '033) for treating asthma, since bronchial smooth muscle cells and vascular smooth muscle cells are equivalent, as taught by Waksman et al., and both asthma and restenosis involve hypertrophy of smooth muscle cells, as taught by James et al. and Regunathan et al., and to move the device while irradiating, since this would allow the treatment longer lesions, thus producing a method such as claimed.

In contrast to the Examiner's assertions, the Dr. Laufer Declaration provides facts which establish (a) the meaning of the applied references to a person of ordinary skill in the art at the time of the invention, and (b) the prevailing view at the time of the invention was that damaging airway walls, such as by debulking of smooth muscle tissue, for purposes of treating asthma may have negative effects because airway smooth muscle tissue was thought to be important for lung function. These facts directly refute Examiner Shay's characterizations of the applied references and hypotheses for the previous and current rejections of the claimed method for treating asthma. As such, because the Dr. Laufer Declaration refutes Examiner Shay's bases for the previous and current rejections of the claimed invention, the Dr. Laufer Declaration is in fact drawn to the patentability of the claimed invention.

Examiner Shay also infers that he was not informed of Dr. Laufer's interest in the pending application. The Examiner is simply incorrect. Ms. Bains prepared notes regarding Dr. Laufer's interest in Asthmatx Inc. before the June 2008 Interview, and Ms. Bains referred to those notes while making introductory statements to Examiner Shay

which forthrightly informed Examiner Shay that Dr. Laufer (a) founded Broncus Technologies, Inc., which became Asthmatx, Inc., (b) is a Board Member of and paid consultant for Asthmatx, Inc., and (c) holds option and stock interests in Asthmatx, Inc., as set forth in Paragraph 4 of the Dr. Laufer Declaration. As such, even though Examiner Shay apparently does not recall Ms. Bains' introductory statements, she fully informed him of Dr. Laufer's interest in the application at the start of the June 2008 Interview.

Examiner Shay further asserts that there was an inference or even express statement during the June 2008 Interview "that the denial by the FDA was for the claimed method." The Examiner appears to infer that there was some nefarious intent during the June 2008 Interview, but the Examiner is again incorrect. Paragraph 9 of the draft of the Dr. Laufer Declaration shown to Examiner Shay during the June 2008 Interview read as follows:

In 1998, the United States Food and Drug Administration also held the prevailing view of the time that airway smooth muscle was important for normal lung function. This was one reason why the United States Food and Drug Administration did not grant Asthmatx, Inc, approval to treat asthma in a human patient by debulking airway smooth muscle tissue until 2005.

The only change between this language and Paragraph 9 in the Dr. Laufer Declaration filed in the USPTO is an additional quote from the United States Food and Drug Administration ("FDA") supporting Dr. Laufer's factual statement. As discussed during the June 2008 Interview, the denial by the FDA is factual evidence that the prevailing view of a person of ordinary skill in the art at the time of the invention was that debulking of smooth muscle tissue for purposes of treating asthma may have negative effects on asthma patients because airway smooth muscle tissue was thought to be important for lung function. The statements regarding the FDA were directed to the FDA's initial assessment that the mechanism of action and the results of the claimed method, namely debulking of airway smooth muscle tissue so as to reduce contraction to treat asthma, were sufficiently controversial that the FDA refused to approve the mechanism of

debulking smooth muscle for treating asthma patients. Thus, the discussion during the June 2008 Interview was not misleading in anyway.

The status of the application in light of the Current Office Action, is as follows:

(A) Claims 29-37, 50 and 52-62 were rejected under 35 U.S.C. § 112, first paragraph;

(B) Claims 29-37, 50 and 52-62 were rejected under 35 U.S.C. § 112, second paragraph;

(C) Claims 30, 32, 33, 35, 37, 52, 53, 56, 58 and 59 were rejected under 35 U.S.C. § 102(b) over Ivanyuta et al., *Effect of Low-Power Laser Irradiation of Bronchial Mucosa on the State of Systemic and Local Immunity in Patients with Chronic Bronchitis* ("Ivanyuta");

(D) Claims 29, 32-34, 37, 50 and 56-59 were rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Waksman and Regunathan;

(E) Claims 30 and 35 were rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Regunathan and U.S. Patent No. 5,422,362 ("Vincent");

(F) Claim 36 was rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Regunathan and Waksman;

(G) Claims 52-55 were rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Regunathan and U.S. Patent No. 5,458,596 ("Lax");

(H) Claims 60-62 were rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Regunathan, U.S. Patent No. 6,008,211 ("Robinson"), and U.S. Patent No. 4,754,065 ("Levenson"); and

(I) Several different combinations of the pending claims were rejected under the doctrine of obviousness-type double patenting as being unpatentable over one or more claims of U.S. Patent Nos. 6,488,739 and 5,972,026, and U.S. Patent Application Nos. 11/614,919; 11/612,620; 11/618,533; 11/609,242; 11/608,606; 11/617/512; 11/562,925; 11/425,345; 11/421,444; 11/398,353; 11/408,668; 11/420,442; 11/361,564; 11/117,905; 10/810,276; 11/562,910; 11/614,914; and 11/534,621.

A. Response to the Rejection Under Section 112, First Paragraph

Claims 29-37, 50 and 52-62 were rejected under 35 U.S.C. 112, first paragraph, on the grounds that the phrase "such that ability of the smooth muscle to contract is reduced" was not described in the originally filed specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the application was filed. The Examiner is incorrect. First, claim 50 was amended in the previous response to read "such that the ability of the airway to contract is reduced." The Examiner accordingly appears to have recycled the previous rejection without considering the amendment to claim 50 even though this amendment was discussed during the June 2008 Interview. Second, as discussed during the June 2008 Interview and noted in the response to the previous Office Action, page 11, lines 5-9, of the originally filed specification reads "[t]he elimination of the smooth muscle tissue prevents the hyperactive airways of an asthma patient from contracting." This clearly shows that the inventor possessed the invention of "debulking smooth muscle tissue" of the asthmatic lung "such that ability of the airway to contract is reduced." Therefore, this rejection should be withdrawn.

B. Response to the Rejection Under Section 112, Second Paragraph

Claims 29-37, 50 and 52-62 were rejected under 35 U.S.C. 112, second paragraph. Claim 50, more specifically, was rejected under Section 112, second paragraph, on the grounds that the phrase "such that the ability of the smooth muscle to contract is reduced" was found to lack positive antecedent basis in the originally filed disclosure. The Examiner

also based this rejection on language that is no longer in claim 50. As such, for the reasons explained above regarding the rejection under Section 112, first paragraph, the originally filed specification clearly provides an adequate understanding of the scope of claim 50 to a person of ordinary skill in the art. With respect to claim 55, this claim has been amended to introduce "a motor." Therefore, the rejections of claims 50 and 55 under Section 112, second paragraph, should be withdrawn.

C. Response to the Section 102(b) Rejection: Ivanyuta

Claims 30, 32, 33, 35, 37, 52, 53, 56, 58 and 59 were rejected under 35 U.S.C. § 103(a) over Ivanyuta. In light of the Notice of Appeal filed concurrently with this paper, this rejection will be substantively addressed in an Appeal Brief filed in accordance with the appeal process.

D. Response to the Section 103(a) Rejection: James, Clarke, Waksman and Regunathan

Claims 29, 32-34, 37, 50 and 56-59 were rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke and Regunathan. In light of the Notice of Appeal filed concurrently with this paper, this rejection will be substantively addressed in an Appeal Brief filed in accordance with the appeal process.

E. Response to the Section 103(a) Rejection : James, Clarke, Regunathan and Vincent

Claims 30 and 35 were rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Regunathan and Vincent. In light of the Notice of Appeal filed concurrently with this paper, this rejection will be substantively addressed in an Appeal Brief filed in accordance with the appeal process.

F. Response to the Section 103(a) Rejection: James, Clarke, Regunathan and Waksman

Claim 36 was rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Regunathan and Waksman. In light of the Notice of Appeal filed concurrently with this paper, this rejection will be substantively addressed in an Appeal Brief filed in accordance with the appeal process.

G. Response to the Section 103(a) Rejection: James, Clarke, Regunathan and Lax

Claims 52-55 were rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Regunathan and Lax. In light of the Notice of Appeal filed concurrently with this paper, this rejection will be substantively addressed in an Appeal Brief filed in accordance with the appeal process.

H. Response to the Section 103(a) Rejection: James, Clarke, Regunathan, Robinson and Levenson

Claims 60-62 were rejected under 35 U.S.C. § 103(a) over the combination of James, Clarke, Regunathan, Robinson and Levenson. In light of the Notice of Appeal filed concurrently with this paper, this rejection will be substantively addressed in an Appeal Brief filed in accordance with the appeal process.

I. Response to Double Patenting Rejections

Claims 29-30, 32-35, 37, 50, and 52-59 were also rejected under the doctrine of obviousness-type double patenting over one or more claims of (a) two issued patents and (b) a number of later filed copending applications. Under MPEP § 804, if the present application is in condition for allowance before issuance of the listed copending applications, then the present application should not be subject to an obviousness-type double patenting rejection over those applications. The present application antedates all of the copending applications listed in the obviousness-type double patenting rejections, and


thus the filing of Terminal Disclaimers regarding the above listed copending applications will be fully addressed upon an indication of allowable subject matter. The applicant respectfully requests a stay of this rejection pending the outcome of the appeal process or an earlier issuance of one of the cited copending applications. With respect to the obviousness-type double patenting rejection over U.S. Patent No. 6,488,739, this rejection is improper because the '739 patent is not owned by Asthmatx, Inc. and is not related to the claimed subject matter. Furthermore, as explained in the response to the previous Office Action, a Terminal Disclaimer was already filed with respect to U.S. Patent No. 5,972,026 in the paper dated 31 October 2007 filed by the applicants in response to the Office Action dated 11 July 2007.

J. Conclusion

The applicant respectfully requests that the foregoing amendments be entered to put the claims in better condition for appeal.

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Respectfully submitted,

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